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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,106	04/19/2004	Gopi M. Venkatesh	451194-107	1448

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,106	VENKATESH ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 10, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/19/2004, 12/19/2005 & 05/08/2006.

DETAILED ACTION

1. Applicant's arguments see page 9-10, filed on April 10, 2007 with respect to the rejection(s) of claims 1-24 under 102(b) and 103(a) have been fully considered but they are not persuasive. Therefore, the rejection(s) are maintained. However, upon further consideration, a new ground(s) of rejection is made in view of changes made in to the scope of the claims.

New ground(s) of rejection is prepared as follow.

Claims Disposition

2. Claims 1-24 are pending and presented for examination.

Information Disclosure Statement

3. Information Disclosure Statement filed on 11/19/2004, 12/19/2005 and 05/08/2006 have been received and entered. The reference cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohta, Motohiro et al. (EP 0 914 818 A1), for the reasons set forth in the Office action mailed on 11/13/2006.

Applicant's arguments filed on April 10, 2007 have fully considered but they are not persuasive.

Applicant asserts that in the process of preparation of final product tablet, unable to identify any taste-masked capsules.

Response:

The prior art cited above discloses a process of preparing a tablet comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns, an active ingredient, a polymeric binder and a disintegrant. Even though the patent does not explicitly teach about a taste-masked microcapsule (the intended use) the patent meets the structural limitations of the instant claims. The Ohta patent discloses a composition comprising at least one drug, one polymeric binder, a disintegrant and compressing the composition into tablets of desired shapes and tablets thus obtained disintegrates in about 10 seconds in oral cavity to release the entire amount of drug. Since all factors that effect the dissolution profile of the instant claims is disclosed by the prior art, so to must the dissolution profile. Since critical structural elements required by the instant invention are taught by Ohta, the tablets produced should inherently have desired dissolution range to obtain a like or similar results without departing from the spirit and the scope of the invention. Same composition must have the same properties.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1,11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta, Motohiro et al. (EP 0 914 818 A1) in view of Cherukuri et al. (US 2002/0044962 A1)

Ohta meets the claim limitations as described above but fails to include pharmaceutically active agent such as sumatriptan.

However, Cherukuri discloses a controlled release encapsulated pharmaceutical composition comprising at least one active ingredient, at one erodible polymer, one lubricating material and said product is in the form of a caplet (see abstract). The preferred therapeutic agent includes sumatriptan, omeprzole, lansoprazole, ranitidine HCl, famotidine, cimetidine and the like (see para 0098 and 0109). And also the encapsulated product may be made with two or more erodible polymers, at least one that erodes quickly in the body to provide immediate dissolution of the drug and at least another that does not erode as quickly, thus delaying release of the active ingredient until a desired time (see para 0086).

At the time of the invention, it would have been obvious by one skilled in the art to modify the composition disclosed by Ohta to incorporate sumatriptan encapsulated pharmaceutical composition because Cherukuri teaches that the incorporation of encapsulated pharmaceutical composition provides advantages of pulses or pulsating release of the active ingredients (i.e.,) the release of active ingredients may be continuous, discontinuous, extended or sustained. One motivation is provided by Cherukuri in that the drug release can be controlled by pulsating delivery of the active ingredient. Additionally the pulsating effect is achieved by incorporating into a standard capsule enpuslated products prepared from different erodible polymers. One skilled in the art would have been motivated to incorporate the sumatriptan encapsulated pharmaceutical composition in the composition advanced by Ohta. Based on the

teaching of Cherukuri, there is reasonable expectation that the sumatriptan encapsulated pharmaceutical composition would be highly desirable and provides a good controlled and extended release characteristics for pharmaceuticals.

7. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Percel et al. (US 6,451,345) in view of Masaki et al. (US 5,466,464), for the reason set forth in the Office action mailed on November 13, 2006.

Applicant's argument filed on April 10, 2007 has been fully considered but they are not persuasive.

Applicant asserts that Percel et al., fails to disclose or suggest a tablet that rapidly disintegrates in the oral cavity and provides an immediate release.

This is not found persuasive because parcel teaches a taste-masked microcapsules suitable for oral administration as a fast disintegrating tablet and release the active ingredient in an hour 2.8% and 76% at pH 4.0 and 6.8 respectively in the mouth. However applicant is reminded the reference is not anticipatory by used to establish the level of skill in the art regarding processing steps and procedures to provide claimed hardness of tablets in general. The reference is relied upon to establish that it is obvious to incorporate the active agent into the present polymeric binder while achieving desired dissolution and bitter taste masking in a single step formulation. Further the reference establishes the knowledge in the art to develop a process for producing tablets having desired dissolution and taste-masking pharmaceutical formulations to form tablets, capsules and suspensions. In the instant case Percel reference in combination with Masaki teaching provides desired dissolution and taste-masking formulations in the form tablets along with similar binders and other common excipients.

Thus, examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It remains the position of the Percel patent by the process of the Masaki patent since both patent disclose taste-masked pharmaceutical formulations in the form of tablets along with similar binders and other common excipients.

Conclusion

1. No claims are allowed at this time.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER